

-continued

Component	% w/w
Abrasive Silica	8.00
TiO <sub>2</sub>	0.35
Carboxymethyl Cellulose	0.90
Glycerin USP	6.00
Peppermint Oil	0.30
Flavor 0.46	
Sodium Lauryl Sulfate	1.5
Deionized Water	21.33

\*~1.3% P<sub>2</sub>O<sub>7</sub><sup>-4</sup> ion.

Several dentifrice compositions were prepared in a manner similar to Example 1, except that the amount of P<sub>2</sub>O<sub>7</sub><sup>-4</sup> ion was varied in a number of the commercially available compositions. These formulations were tested against a regular toothpaste (which contains no pyrophosphates) and a tartar control toothpaste (which contains a mixture of tetrasodium pyrophosphate, tetrapotassium pyrophosphate and disodium pyrophosphate) in rat studies.

The rat studies were conducted by applying each composition to the teeth of individual rats with a cotton swab each morning and afternoon for 5 days a week for a three week period. The calculus formation was scored according to the method of Francis and Briner, Journal of Dental Research, Vol. 48, 1185-1195 (1969). The results are set forth in Table I.

TABLE I

Composition	pH	% P <sub>2</sub> O <sub>7</sub> <sup>-4</sup>	Mean Calculus Score	% Reduction vs. Control
A	7.7	3.3%	34.13	48.3%
B	7.7	1.3%	44.57	32.5%
C	7.7	0.0%	66.03	—
Tartar Control Toothpaste	7.6	5.0%	47.57	28.0%
D	7.7	3.3	45.00	35.3%
E	7.7	1.3%	49.22	29.2%
Regular Toothpaste	6.9	0%	69.57	—
Tartar Control Toothpaste	7.6	5.0%	38.03	45.3%

The results of the rat calculus studies indicate that the formulation of this invention, i.e. Compositions B and E, were effective at reducing calculus formation even when only 1.3% P<sub>2</sub>O<sub>7</sub><sup>-4</sup> ions are present.

## EXAMPLE 2 AND COMPARATIVE EXAMPLE 1

Two dentifrice composition were prepared containing the following components:

Components	% w/w	
	Ex. 2	Comp. Ex. 1
Thymol	0.30	0.30
Methyl Salicylate	0.05	0.05
Menthol	0.16	0.16
Eucalyptol	0.09	0.09
Tetrapotassium Pyrophosphate	2.47*	6.40**
Sodium Fluoride	0.24	0.24
Sodium Saccharin	0.60	0.60
Polyethylene Glycol 1450 NF	3.00	3.00
Sorbitol Solution (70%)	45.00	40.00
Gelling Silica	8.5	8.00
Abrasive Silica	8.0	8.00

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Components	% w/w	
	Ex. 2	Comp. Ex. 1
TiO <sub>2</sub>	0.35	0.35
Carboxymethyl Cellulose	0.90	0.90
Glycerin USP	6.00	6.00
Peppermint Oil	0.26	0.26
Spearmint Oil	0.09	0.09
Flavor 0.50	0.50	
Sodium Lauryl Sulfate	1.50	1.50
Phosphoric Acid	—	0.73
Deionized Water	21.98	22.83

\*1.3% P<sub>2</sub>O<sub>7</sub><sup>-4</sup>\*\*3.3% P<sub>2</sub>O<sub>7</sub><sup>-4</sup>

The dentifrice composition of Example 2 and Comparative Example 1 were tested for calculus inhibition in a clinical study along with the previously described regular toothpaste and the tartar control toothpaste. The study was divided into two fourteen day phases with a seven day wash-out period between each phase. A dental prophylaxis of teeth #21-28 was conducted prior to performing each phase. On day 14, the facial and lingual surfaces of teeth #22-27 were evaluated for calculus accumulation using the method according to Francis and Briner. During phase 1, all subjects delivered a conventional silica based NaF dentifrice (control) to the lower anterior teeth via a custom-fitted mouthguard, i.e., a tooth shield, and brushed only the teeth that remained exposed twice a day. In the second phase, subjects were separated into four treatment groups on the basis of the phase 1 V-M scores. The subjects then delivered the compositions using the tooth shield in manner described above, with one group continuing to use the control. The results of the clinical tests are set forth in Table II.

TABLE II

Composition	pH	% P <sub>2</sub> O <sub>7</sub> <sup>-4</sup>	Mean Calculus Score	% Reduction vs. Control
Ex. 2	8.1	1.3%	15.47	25.4%
Comp. Ex. 1	7.7	3.3%	16.85	18.8%
Regular Toothpaste	6.9	0.0%	20.75	—
Tartar Control Toothpaste	7.6	5.0%	16.19	21.9%

The clinical results indicate that the dentifrice composition of this invention provides excellent calculus inhibition even with only 1.3% pyrophosphate ion derived from the highly soluble tetrapotassium pyrophosphate.

Other variations and modifications of this invention will be obvious to those skilled in this art. This invention is not limited except as set forth in the following claims.

What is claimed is:

1. An anticalculus dentifrice comprising:

- (a) an antimicrobial agent comprising thymol, eucalyptol, methyl salicylate and menthol,
- (b) a pyrophosphate ion in an anticalculus effective amount from about 0.1% to less than 1.5% by weight of the composition,
- (c) one or more fluoride-releasing compounds,
- (d) a dental abrasive, and
- (e) an orally acceptable vehicle;

wherein the composition is free of an anticalculus enhancing agent, has a pH of about 7.5 to about 10 and the pyrophosphate ion is derived from an alkali metal pyrophosphate salt having an aqueous solubility greater than 200 g/kg at 25° C.